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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,847	08/09/2006	Philipp Kropf	03728/0205090-US0	7019
7278 7590 09/29/2008 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER WOLF, MEGAN YARNALL	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 09/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/597,847

Applicant(s)

KROPF ET AL.

Examiner

MEGAN WOLF

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-36 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-36 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/12/08 has been entered.

Response to Arguments

2. Applicant's arguments with respect to Lakin disclosing a less than hemispherical shell and a free edge of the crown lying in the same plane as a free edge of the shell section have been fully considered and are persuasive. The 35 U.S.C. 102(b) rejection of claims 18 and 36 has been withdrawn as well as the 35 U.S.C. 103(a) rejection of claims 19-21, 35, 40, and 42 in view of Lakin.

3. Applicant's arguments regarding the rejection of claims 18-42 over Sutter in view of Lakin have been fully considered but they are not persuasive. Applicant argues that the limitation of the free edge of the crown lying in the same plane as a free edge of the shell section does not merely describe the size of the various components. However, the Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the length of the crown of Sutter in order to minimize the amount of required bone resection as discussed in the final office action. It is well known in the art, and specifically taught in Lakin as discussed on page 7 of the

final office action, to decrease the amount of necessary bone resection by decreasing the size of the prosthetic components. Further, the device of Sutter is specifically directed to minimizing the amount of resected bone in order to prevent weakening of the femur (col.1, ll.12-17). Sutter also teaches that the portion shown as extending beyond the plane of the shell "s" is desirably less than 40% of the length of the crown (col.5, ll.17-19). This range means that varying the length of the crown is within the scope of the device of Sutter. By placing a limit on the length, this range also implies that the crown should be as short as possible depending on the health of the patient's bone, and may also be interpreted as including 0% of length L which would position a free edge of the crown in the same plane or within the plane of the free edge of the shell. The Examiner maintains that it would have been obvious to simply modify the length of the crown in order to minimize bone resection and prevent weakening of the femur.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. 4,332,036 in view of Lakin 2003/0163202.

6. Re claim 18, Sutter discloses the invention substantially as claimed including prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in

an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14) and crown 7 that partitions the cavity of the shell section into first and second cavities capable of receiving bone (fig.6) wherein the shell is hemispherically shaped (fig.1). However, Sutter does not specifically disclose that the shell section comprises less than a hemisphere and that a free edge of the crown lies in the same plane as a free edge of the shell section.

Lakin discloses a prosthesis for replacing a surface of a ball in a ball-and-socket joint, in the same field of endeavor, wherein the shell section may be in the form of a partial hemisphere (par.32) for the purpose of providing a partial hip replacement that conserves healthy bone tissue for future revision procedures and minimizes the amount of tissue that is required to be removed (par.8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hemispherical head of Sutter to be less than hemispherical as taught by Lakin in order to minimize the amount of bone tissue resection. Regarding the length of the crown, Sutter discloses the free edge of crown 7 extending between 0% and 40% of the length of the crown which means that the crown may lie in the same plane as the free edge of the shell (col.5, ll.17-19). Further, it has been held that limitations relating to size are not sufficient to patentably distinguish over the prior art (In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A). It would also have been obvious to one of ordinary skill in the art at the time of the invention to modify the length of the crown to accommodate different patient anatomy. For instance, if a patient has a smaller femur, a shorter crown length would be more appropriate.

Finally, if the patient has a sufficient amount of healthy bone tissue, a shorter crown length will allow for less healthy bone to be resected which helps maintains the strength and integrity of the bone.

7. Re claims 19-21, as Sutter in view of Lakin discloses the general conditions of the claims wherein the shell is less than a hemisphere, it would have been obvious to one of ordinary skill in the art to modify the size of the partial hemispherical shell to include the claimed ranges as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).
8. Re claim 22, Sutter further teaches prosthesis 1 wherein first cavity 7 has a circular shape and second cavity 3c has an annular shape (fig.1).
9. Re claim 23, Sutter further teaches prosthesis 1 wherein innermost end of the crown 7b is integrally connected to the inner surface of the shell section so as to form a single integral structure (col.3, ll.25-27).
10. Re claim 24, Sutter further teaches prosthesis 1 wherein at least one of the inner surface of the shell section and a surface of the crown is configured for contact with the bone end and is therefore a roughened surface (col.5, ll.46-50).
11. Re claim 25, Sutter further teaches prosthesis 1 wherein the crown has at least one opening 7e formed therein to provide communication between the first and second cavities (fig.1).

12. Re claim 26, Sutter further teaches prosthesis 1 wherein the at least one opening comprises at least five openings (figs.1, 20).
13. Re claim 27, Sutter further teaches prosthesis 1 wherein at least one of an inner surface and an outer surface of the crown has a relief structure formed as a part thereof (col.7, ll.26-31).
14. Re claim 28, Sutter further teaches prosthesis 1 wherein the relief structure comprises a fluting that is formed by ring beads that extend circumferentially around the crown (col.7, ll.26-31; fig.11).
15. Re claim 29, Sutter further teaches prosthesis 1 wherein the inner surface of the shell section includes a relief structure that extends along an edge of the shell section (col.3, ll.53-60; col.6, ll.1-17; figs. 7, 11).
16. Re claim 30, Sutter further teaches prosthesis 1 wherein the relief structure comprises fluting formed circumferentially around the inner surface of the shell section (figs. 2, 7, 11).
17. Re claim 31, Sutter further teaches prosthesis 1 wherein the crown and shell section are separate parts and are constructed to be securely coupled to one another (col.3, ll.25-27).
18. Re claim 32, Sutter teaches the invention as claimed and as discussed above. Sutter does not teach a prosthesis wherein the crown and shell section are constructed to be threadingly coupled to one another by means of threads formed on at least one of an outer surface of the crown and the inner surface of the shell section.

Lakin teaches a screw locking mechanism for the purpose of coupling two components together (par.34, ll.1-4). While the location of the threads is not positively disclosed as being on an outer surface of the crown and/or the inner surface of the shell section, it would have been a matter of design choice to place the threads in either location, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B). Further, it has been held that making parts separable for any desirable reason is an obvious extension of prior art teachings (In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) MPEP V C).

Therefore, it would have been obvious at the time of the invention to modify Sutter in view of Lakin in order to hold the components together without any appreciable movement as taught by Lakin, par.34, ll.4-6.

19. Re claim 33, Sutter further teaches prosthesis 1 wherein the crown has a circular shape (col.3, l.22).
20. Re claim 34, Sutter further teaches prosthesis 1 wherein the crown is arrayed in a coaxial manner (col.3, ll.22-23; fig.1).
21. Re claim 35, see the rejection of claim 32 above.
22. Re claims 36 and 40, Sutter teaches prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14), and crown 7 that

partitions the cavity of the shell section into first and second cavities adapted to receive portions of the bone end (fig.1), wherein shell section 3 is hemispherical (col.3, ll.17-19) and a free edge of the crown is displaced (s) from a plane in which a free edge of shell section 3 lies (fig.3). Regarding the limitation wherein the shell section comprises less than a hemisphere, see the rejection of claim 18 above with respect to the teachings of Lakin for minimizing bone resection with smaller components. Regarding the limitation wherein the crown does not intersect a plane in which the free edge of the shell section lies, see the rejection of claim 18 above which discusses that Sutter teaches that the crown need not extend beyond the plane of the shell and that it would have been obvious to vary the length of the crown to minimize the amount of necessary bone resection to preserve the integrity of the bone.

23. Re claim 41, Sutter further teaches a procedure for implantation of a prosthesis in a bone comprising the steps of: preparing the bone and forming a groove in the bone (col.5, ll.4-14; figs. 4, 5); providing prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint, prosthesis 1 including spherical shell section 3 and crown 7, shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14); crown 7 partitioning the cavity of the shell section into a first cavity and a second cavity (fig.1), wherein a shape of shell section 3 is hemispherical (col.3, ll.17-19) and a free edge of crown 7 lies outside the plane of the free edge of shell section 3 (fig.1); and inserting the prosthesis onto the bone such that the crown is received in the groove formed in the bone (col.5, ll.14-17; fig.6). Regarding the limitations wherein the

shell is less than a hemisphere and the crown lies in the same plane as a free edge of the shell, see the rejection of claim 18 above.

Conclusion

24. This is a continuation of applicant's earlier Application No. 10/597847. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN WOLF whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
9/25/08

/Bruce E Snow/
Primary Examiner, Art Unit 3738